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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,894	03/09/2004	Joachim Brendel	DEAV2003/0023 US NP	2872

5487 7590 06/10/2010

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EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/796,894	BRENDEL ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 3/4/10, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 - New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, “cardioprotective” does not appear to be supported by the specification. Examiner notes the specification discloses treatment of various conditions, such as atrial arrhythmias, including atrial fibrillation and atrial flutters, but disclosure of a few species does not provide written support for the broader class of being a “cardioprotective” preparation which could reasonably include other conditions, such as hear attacks (for example, see pg 5 lines 1-10 of the instant specification).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al (US 6,531,495, '495, filed Oct 30, 2000, granted 3/11/2003), in view of Smith et al (US Pregrant Pub 2002/0161018).

Applicants assert the synergistic result is now claimed, as the preamble is amended to recite "cardioprotective pharmaceutical preparation" for intravenous administration to a mammal. Applicants then assert the court in In re Kollman overturned a finding that limited experiment data does not support broader claims where the court reasoned the skilled artisan would reasonably extend the probative value of data presented to a reasonable range. Applicant further asserts Examiner has failed to present any evidence showing why the skilled person would doubt the data provided does not fully support the current scope of claim 5.

Examiner disagrees. First, Examiner notes the amendment of the "carioprotective" is in the preamble, and as such, is directed to a single intended use. Thus, where the required limitation is "synergistic combination", it is still unclear what "synergy" is required and could include other properties, such as increased solubility or unexpected increase in stability. Thus, Applicants recitation of a "synergistic combination" is not sufficiently linked to the recited intended use to provide a sufficient nexus to be considered relevant. Examiner suggests removing the term "synergistic", given the synergy of administration is better suited as rebuttal to the obviousness

rejection, given a composition claim cannot have an active step of administering to a patient, which would provide the requisite nexus between the disclosed synergistic effect and the composition.

Further, even if the dosage of the ibutilide or dofetilie were linked to the conditions disclosed in the specification, the claims are still open to additional agents, which would affect the requisite dosage amounts. Thus, Examiner suggests amending the claims to include the dosage taught by the specification.

Second, unlike the factual situation of In re Kollman, the experiment data provided herein does not support the breadth of the claims given the skilled artisan could not reasonably extend the probative value of the data presented to the range encompassed by the claimed subject matter. While the data presented to the court provided numerous values that allowed a pattern to be established, here, the ibutilide and dofetilide are administered at only one dosage. Further, the range claimed in the In re Kollman claims was a limited range. Thus, the single data point of evidence presented is significantly less than in the prosecution of In re Kollman, and one data point for the amount of ibutilide or dofetilide would not reasonably be interpreted by the skilled artisan to include all possible dosages, as instantly claimed.

Further, Examiner notes if a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. MPEP 2145. As such, the burden rests on Applicant to present evidence to support the assertion that there is a recognizable trend based on the evidence presented. Again, Examiner asserts that Applicant has failed to rebut the

obviousness rejection by presenting a single data point which would not provide the skilled artisan with any expectation that the trend would follow beyond the single concentration.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612